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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/486,070	06/07/1995	JANNIS G. STAVRIANOPOULOS	ENZ-7(P)(C3)	6279
28171	7590	04/07/2004	EXAMINER	
ENZO BIOCHEM, INC. 527 MADISON AVENUE (9TH FLOOR) NEW YORK, NY 10022			MARSCHER, ARDIN H	
			ART UNIT	PAPER NUMBER

1631

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

08/486,070

Applicant(s)

STAVRIANOPOULOS ET AL.

Examiner

Ardin Marschel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2003 and 27 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 2161-3143 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2161-3143 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br><u>Refer to the Date (6/2/04)</u> | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicants' arguments, filed 10/31/03 and 1/27/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### **NEW MATTER**

Claims 2161-3143 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Consideration of the entirety of the instant application as filed has revealed that several citations therein are directed to non-porous solid supports with nucleic acids. These citations as discussed below do not give written basis for the generic non-porous solid support embodiments as instantly claimed wherein nucleic acids are fixed or immobilized in hybridizable form. A citation of non-porous solid support is present on page 10, lines 17-22, wherein the non-porous solid supports are also required to be transparent and also only fixation is cited thereto, rather than immobilization also as instantly claimed. On page 14, lines 26-29, a non-porous solid support is cited but only with a directly fixed polynucleotide in hybridizable form again not supporting the newly submitted claims. On page 15, lines 13-15, non-porous supports are also required to be

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translucent or transparent. On page 22, last 4 lines, the non-porous solid supports are limited to being siliceous and also provided with a treatment of a coating of epoxy resin. On page 23, lines 12-16, the non-porous solid support is limited via direct fixation of a polynucleotide. In claim 5 as originally filed the dependence from claim 1 causes the embodiments therein to be limited to fixed polynucleotides to a non-porous support without additionally an immobilization option. This is the same set of limitations present in claim 24 as originally filed. No other non-porous embodiments have been found as filed to support the broad generic embodiments wherein a generic non-porous support is either fixed (no direct limitation, for example) to a nucleic acid. This rejection is necessitated by amendment.

Additionally, certain claims such as claim 2494 and many others cite reactive sites or binding sites on the non-porous solid support embodiments. Consideration of the entirety of the instant disclosure as filed has failed to reveal such generic reactive or binding sites disclosure. It is noted that certain chemical treatments of solid supports are disclosed, however, reactions supported by these treatments are covalent in nature and not generic without any covalent limitation. Additionally, the only binding practice separate from reactive covalent attachment practice as filed is that of hybridization between nucleic acid polymers. These limitations therefore are NEW MATTER as being broader and more generic than such sites as disclosed as originally filed. This rejection is necessitated by amendment.

Consideration of array claim 2715 reveals that it is directed to a generic non-porous solid support with various single-stranded nucleic acids or sequences fixed or

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immobilized thereto. Reiterated consideration of the entirety of the instant disclosure reveals that the practice of "various denatured analytes" with a solid support is disclosed only on page 16, lines 9-14, as being present for example in an array of depressions or wells. A generic solid support is not disclosed as filed nor a non-porous generic support of this type with "various single-stranded nucleic acids or sequences" as now present in claim 2715 and others via dependence, such as claim 2825 and claims dependent therefrom. Review of instant claim 2933 directed to wells or depressions with said "various..." limitations reveals that the nucleic acid strands or sequences are either fixed or immobilized whereas in contrast said page 16 citation only cites fixation practice. Thus claims 2933 also contains NEW MATTER for this reason. This rejection is necessitated by amendment which set forth such "various..." limitations.

NEW MATTER has also been added in newly submitted claims via independent claim 3030. Several citations as filed are directed to glass or plastic solid supports but none of them support instant claim 3030. For example, on page 10, lines 17-22, glass or plastic solid supports are set forth but only with fixed, and not immobilized nucleic acids or sequences. Additionally, these solid supports are disclosed as being non-porous but such a non-porous limitation is lacking in claim 3030. It is noted that glass and plastic are well known to be optionally porous as well as non-porous, if desired. On page 15, lines 16-20, glass is cited as being only "fixed" to a denatured single-stranded "DNA" sequences which again fails to support instant claim 3030 as to written basis. Glass plates are cited on page 16, lines 8-14, but limited to containing well or depressions and lacking in generic support of instant claim 3030. On pages 16-17

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Example 2 cites a glass surface but is specifically treated and in the form of glass tubes. In Example 3 again the glass is specifically treated with DNA immobilized. In Example 5 on pages 20-21 a probe is immobilizes to a non-porous plastic surface. Claim 3030 lacks any non-porous limitation. On page 22, line 1, DDA-coated polystyrene is cited but this also is not supportive of the generic instant claim 3030. In Example 7 a microtiter well is cited but only with polynucleotide fixation thereto again not supportive of instant claim 3030. Original claim 7 cites glass or plastic, however, this claim depends from claim 5 which also has a non-porous limitation which is not present in instant claim 3030. This rejection is necessitated by amendment.

Applicants argue the previously set forth rejections, however, are deemed moot due to new rejections as set forth above as necessitated by amendment.

The Declaration of Dr. Dollie M. W. Kirtikar has been considered. It describes experimental data and embodiments which are apparently separate from the instant disclosure as filed. This rejection is based on a lack of written description of specific claim limitations as filed. The additional information of experiments performed by Dr. Kirtikar are non-persuasive as these were not disclosed as filed and therefore fail to remedy the lack of written basis for limitations of the instant claims. For specific example, item # 7 of the Declaration describes Exhibits, none of which are set forth in the instant application. Within these exhibits the first Exhibit 2 indicates the usage or preprinted slides including with slots. No such slotted slides have been pointed to as being instantly disclosed as filed and therefore fails to be persuasive. It is appreciated that the experimental material cited in said Declaration is consistent with the instant

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application, however, this lacks persuasiveness as only the written description as filed must be relied on for the purposes of this rejection.

#### INFORMATION DISCLOSURE STATEMENT

An executed PTO Form 1449 is enclosed herewith which was previously inadvertently overlooked but now has been considered.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.**

See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Since the fee set forth in 37 CFR 1.17(r) for a first submission subsequent to a final rejection has been previously paid, applicants, under 37 CFR 1.129(a), is entitled to have a second submission entered and considered on the merits if, prior to abandonment, the second submission and the fee set forth in 37 CFR 1.17(r) are filed prior to the filing of an appeal brief under 37 CFR 1.192. Upon the timely filing of a second submission and the appropriate fee for a large entity under 37 CFR 1.17(r), the finality of the previous Office action will be withdrawn. If a notice of appeal and the appeal fee set forth in 37 CFR 1.17(e)

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were filed prior to or with the payment of the fee set forth in 37 CFR 1.17(r), the payment of the fee set forth in 37 CFR 1.17(r) by applicant will be construed as a request to dismiss the appeal and to continue prosecution under 37 CFR 1.129(a). In view of 35 U.S.C. 132, no amendment considered as a result of payment of the fee set forth in 37 CFR 1.17(r) may introduce new matter into the disclosure of the application.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

April 2, 2004

*Ardin H. Marschel* 4/4/04  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER